

**Section 5      510(k) Summary**

**MAY 06 2013**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K124016

<b>Submitted by:</b>	DJO, LLC 1430 Decision Street Vista, CA 92081
<b>Contact Person:</b>	Maria Pronina Regulatory Affairs Specialist Phone: 760-734-3047 Fax: 760-734-5694
<b>Date Summary Prepared:</b>	December 21, 2012
<b>Trade Name:</b>	Empi Phoenix
<b>Common/Usual Name:</b>	NMES; TENS
<b>Classification Name:</b>	Powered muscle stimulator (21 CFR 890.5850); Transcutaneous electrical nerve stimulator for pain relief (21 CFR 882.5890)
<b>Product Code:</b>	IPF, Powered muscle stimulator GZJ, Transcutaneous electrical nerve stimulator for pain relief NYN, Stimulator, electrical, transcutaneous, for arthritis
<b>Regulatory Class:</b>	Class II
<b>Predicate Device(s):</b>	Compex® Rehab (K090632) EMPI Continuum (K093324)

### **Device Description:**

The Empi Phoenix is a multifunctional electrotherapy device indicated for retarding or preventing disuse atrophy, maintaining or increasing range of motion, and re-educating muscles. The Empi Phoenix device provides two channels of neuromuscular electrical stimulation (NMES), transcutaneous electrical stimulation (TENS) for pain management, and a pulsed DC Edema program to increase local blood circulation and reduce edema (swelling). These programs allow the patient to receive electrotherapy throughout the recovery cycle using a single device.

Its simplified programming makes the Empi Phoenix device convenient for home use: after placing the electrodes and selecting the program as prescribed by a healthcare professional, the patient only needs to increase the intensity to begin therapy. The device may be used with conventional leadwires and electrodes. For NMES treatment, it also may be paired with the Empi Phoenix™ Thigh Garment (provided as an accessory), which is designed to make electrode placement and treatment of the knee/quadriceps easier for the patient and clinician.

### **Intended Use:**

*As an NMES device, indications are for the following conditions:*

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation

*As a TENS device, indications are for the following conditions:*

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

*As a pulsed current device, indications are for the following conditions:*

- Reduction of edema (under negative electrodes)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance of increase of range of motion

### **Technological Comparison to Predicate Devices:**

The Empi Phoenix device is technologically equivalent to Compex® Rehab (K090632) and EMPI Continuum (K093324) with respect to technical and performance characteristics.

The Empi Phoenix and the Compex Rehab have the same NMES indications for use. Both are hand-held devices. The Empi Phoenix uses two AA batteries that must be removed from the device for recharging. The Compex Rehab uses one 4.6 V NiMH battery that is charged in the device. The Empi Phoenix is a simpler form of the Compex Rehab. The Phoenix provides two channels of stimulation instead of four. For the Phoenix, the user only needs to select the desired program and adjust the intensity. On the Compex Rehab, the user has several display options and must choose the appropriate body part before selecting the program. The progression of warm-up, work (contraction alternating with active rest), and cool down is the same on the two devices.

The Empi Phoenix and Empi Continuum devices both provide TENS and Pulsed DC treatments. Both are 2-channel devices using two removable AA batteries. Both have an optional remote switch. The Phoenix is more convenient for home use because the user only needs to select the program and the intensity. The Continuum can be locked by the clinician so that the user only has these options, but if the device is not locked, the Continuum has more display and parameter choices for the user.

For TENS, the Continuum offers five body-part specific programs and one custom program. All programs have adjustable treatment time and frequency, and the custom program also allows the selection of type and degree of modulation and cycling time. Both devices use a fixed pulse duration of 300  $\mu$ s. The type of modulation is different between the two devices. Continuum uses either intensity modulation or a simple modulated pulse (SMP) which modulates both frequency and intensity. The Phoenix uses frequency modulation. The purpose of modulation in a TENS treatment is to reduce the body's acclimation to the signal, and either type of modulation can do this effectively.

For PDC, the Continuum and the Phoenix both provide 266  $\mu$ A of dc current regardless of the amplitude. The Continuum does this by mixing triphasic (2 positive 60  $\mu$ sec pulses and one negative one) and biphasic (one positive and one negative pulse) waveforms. The Phoenix achieves the same result by adjusting the pulse width of the positive waveform compared to the set 60  $\mu$ sec negative pulse width. On the Continuum, the user selects between acute or chronic edema and the software provides net positive or net negative dc waveforms. The Phoenix always generates a net positive waveform, and the user connects the leadwires to the electrodes differently for acute or chronic edema.

The Phoenix and both predicate devices use a microprocessor and a transformer to generate symmetrical square biphasic waveforms for NMES and TENS. All devices use an LCD to display the selected program, remaining time, and channel intensity, and to show open load and low battery icons.

#### **Performance Testing:**

- The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software validation tests demonstrated that the software version meets its design requirements.
- A Human Factors and Usability Study was conducted to validate the usability of the Empi Phoenix device in the home environment. The results of the Summative Validation support the instructions for successfully using the device as intended. The result of the Human Factors and Usability Study substantiates the acceptability of the risks identified during the risk assessment activities.
- The Empi Phoenix was tested and found to comply with the following standards:
  - IEC 60601-1 for basic safety and essential performance
  - IEC 60601-1-2 for electromagnetic compatibility
  - IEC 60601-1-11 for use in a home healthcare environment
  - IEC 60601-2-10 for performance of nerve and muscle stimulators

#### **Conclusion:**

Based on the performance testing and the supporting documentation, it can be concluded that the Empi Phoenix device is safe, effective and substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

May 6, 2013

DJO, LLC  
Attention: Ken Fisher  
SVP Quality Assurance and Regulatory Affairs  
1430 Decision Street  
Vista, CA 92081

Re: K124016  
Trade/Device Name: Empi Phoenix  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered Muscle Stimulator  
Regulatory Class: Class II  
Product Code: IPF, GZJ, NYN  
Dated: March 13, 2013  
Received: March 27, 2013

Dear Mr. Fisher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to:

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joyce M. Whang -S**

for Victor Krauthamer, Ph.D.  
Acting Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

#### Section 4 Indications for Use

510(k) Number (if known): K124016

Device Name: Empi Phoenix

The Empi Phoenix is a multifunctional electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS) and pulsed current stimulation (PCS).

*As an NMES device, indications are for the following conditions:*

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation

*As a TENS device, indications are for the following conditions:*

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

*As a pulsed current device, indications are for the following conditions:*

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance of increase of range of motion

Prescription Use   X   AND/OR Over-the-Counter Use             
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Joyce M. Whang -S**

K124016

Empi Phoenix  
Abbreviated 510(k): New Device

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